

Reply to Office Action of September 15, 2009

### **REMARKS**

Claims 5, 7, and 13 will be pending in the above-identified application upon entry of the present amendment. Claim 5 has been amended to recite that an individual has all three claimed symptoms rather than at least one. Claims 9-11 have been cancelled herein. Therefore, no new matter has been added. Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

### **Drawings**

Since no objection has been received, Applicants assume that the drawings are acceptable and that no further action is necessary. Confirmation thereof in the next Office Action is respectfully requested.

### **Issues under 35 U.S.C. § 103(a)**

Claims 5, 7-11, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueda et al. '103 (US 6,831,103) in view of Hamilton (J. Neurol. Neurosurg Psychiat, 1960, 23, 56). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

### **Legal Standard for Determining Prima Facie Obviousness**

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

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Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

Distinctions over the Cited References

The present invention is directed to a method for treating an individual with a mood disorder having at least three specific symptoms by administering an effective amount of a composition comprising theanine to the individual in need of treatment, wherein said mood disorders are distinct from mood disorders associated with menstruation and the individual is a normofolatemetic patient, as recited in claim 5. Ueda et al. '103 fail to disclose each and every element of claim 5.

The relationship between lack of folate and depression has been discussed in many references. For example, enclosed herewith is a journal article by Alpert et al. titled "Nutrition and Depression: The Role of Folate." Specifically, a low folate level due to poor nutrition is known as a cause of depression, and many patients suffering from depression have a low folate level. Further, it is also known that the conditions of patients suffering from depression due to a low folate level are improved by providing a folate preparation. However, among patients suffering from depression, normofolatemetic patients exist, and one of ordinary skill in the art would not provide a folate preparation to such normofolatemetic patients.

In contrast, the theanine of the present invention exhibits unexpectedly significant amelioration in the symptoms of normofolatemetic patients. This effect is unexpected and unpredictable in view of Ueda et al. '103. As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Furthermore, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results.

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To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Ueda et al. '103 in view of Hamilton fail to disclose all of the claim limitations of independent claim 5, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

### **Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Registration No. 58,258, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

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If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: MAR 11 2010

Respectfully submitted,

#28977

By 

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Attachment: Alpert et al., "Nutrition and Depression: The Role of Folate."